



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

12

Food and Drug Administration
Rockville MD 20857

APR - 2 1991

Re: Ganite
Docket No. 91E-0124

Charles E. Van Horn
• Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

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OFFICE OF THE ASSISTANT
COMMISSIONER FOR PATENTS

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,529,593 filed by Sloan-Kettering Institute for Cancer Research under 35 U.S.C. 156. The human drug product claimed by the patent is Ganite (gallium nitrate), New Drug Application (NDA) No. 19-961.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the active ingredient, gallium nitrate.

The NDA was approved on January 17, 1991, which makes the submission of the patent term extension application on March 7, 1991, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: John P. White
Cooper & Dunham
30 Rockefeller Plaza
New York, NY 10112